MAR - 3 2004

K032-840

12. SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation: September 9, 2003

Device Name: Atrion Medical QL® Inflation Device

Classification Name: Balloon Inflation/Deflation Device

Manufacturer:
Atrion Medical Products, Inc.
PO Box 564, 1426 Curt Francis Road
Arab, AL 35016

Contact:
Mr. Dan Clark,
Atrion Medical Products, Inc.
1426 Curt Francis Road
Arab, AL 35016
Telephone: (256) 586-1580, ext. 220
Fax: (256) 586-8529
Email: dclark@atrionmedical.com

Predicates:

Atrion Medical Products Balloon Catheter Inflation Device, K972964.
Ryder International (Bard Eagle) Urological Balloon Catheter Inflation Device, K962611
Ryder International (USCI Ideal) Balloon Catheter Inflation Device, K953522
Scimed Encore 26 and Encore 30 Inflation Devices, K955869

Device Description:
The Atrion Medical QL® Inflation Device consists of a plastic syringe with a screw-type plunger and a locking lever and rotating palm grip that control the plunger, a manometer to measure pressure and a connecting tube.

Intended Use:

The Inflation Device is recommended for use with balloon dilatation catheters to create and monitor the pressure in the balloon and to deflate the balloon.

Technological Characteristics:
The Atrion Medical QL® Inflation Device has an operating pressure range of vacuum to 40 atm, depending on the manometer attached, while the predicate devices have a range of vacuum to 10 or 30 atm, depending on the predicate. There are no other significant technological characteristics that distinguish the two devices, and no differences that should pose a risk to patient safety.

Testing:

The materials of the device which contact the solution in use have been tested using USP guidelines and the results of these studies indicate that the product is safe for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2004

Mr. Dan Clark
Vice President Regulatory and Quality
Atrion Medical Products, Inc.
P.O. Box 564
1426 Curt Francis Road
ARAB AL 35016

Re: K032840
Trade/Device Name: Atrion Medical QL® Inflation Device
Regulation Number: 21 CFR §876.5520
Regulation Name: Urethral dilator
Product Code: 78 KOE
Regulation Number: 21 CFR §870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: II
Product Code: 78 MAV
Dated: January 14, 2004
Received: January 16, 2004

Dear Mr. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

13. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032840

Device Name: Atrion Medical QL® Inflation Device

Indications For Use:

The Inflation Device is recommended for use with balloon dilatation catheters to create and monitor the pressure in the balloon and to deflate the balloon.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sig
Division of Re ctive, Abdominal,
and Radiological Devices
510(k) Number K032840